Proposed Registration Decision PRD2015-16

Mono- and Di-Potassium Salts of Phosphorus Acid

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Overview

Proposed Registration Decision for Mono and Di-Potassium Salts of Phosphorus Acid

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Winfield Phosphite TGAI and Confine Extra Fungicide, containing the technical grade active ingredient mono- and di-potassium salts of phosphorous acid, to suppress oomycete diseases on a range of crops and ornamentals in greenhouses.

Winfield Phosphite TGAI (Registration Number 30652) and Confine Extra Fungicide (Registration Number 30648), previously known as Winfield Phosphite Colorless, are registered for use in Canada on field grown crops and outdoor ornamentals. The original review for Winfield Phosphite TGAI and Confine Extra Fungicide can be found in Proposed Registration Decision PRD2012-25, *Mono- and Di-Potassium Salts of Phosphorous Acid* and Registration Decision RD2013-10, *Mono- and Di-Potassium Salts of Phosphorous Acid*. The current applications were submitted to add the major new use in greenhouses (Use Site Category 5 – Greenhouse Food Crops and Use Site Category 6 – Greenhouse Non-Food Crops).

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Winfield Phosphite TGAI and Confine Extra Fungicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on mono and di-potassium salts of phosphorus acid, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on mono and di-potassium salts of phosphorus acid, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Are Mono- and Di-Potassium Salts of Phosphorus Acid?

Mono- and di-potassium salts of phosphorous acid is a fungicide active ingredient classified as a phosphonate and used in Confine Extra Fungicide to suppress oomycete diseases on a wide range of crops.

Health Considerations

Can Approved Uses of Mono- and Di-Potassium Salts of Phosphorus Acid Affect Human Health?

Mono- and di-potassium salts of phosphorous acid is unlikely to affect human health when used according to label directions.

Exposure to mono- and di-potassium salts of phosphorous acid may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Mono- and di-potassium salts of phosphorous acid is of low toxicity by the oral, dermal and inhalation routes, and minimally irritating to the eyes. The available information suggests that it is unlikely to have any short-term or prenatal developmental effects, as well as any significant genotoxic effects. The precautionary label statement indicating that contact with skin, eyes, and clothing must be avoided, and the personal protective equipment statement that applicators and other handlers must wear a long-sleeved shirt, long pants, gloves, shoes plus socks, and protective eyewear are effective mitigative measures to reduce the risk associated with the use of mono- and di-potassium salts of phosphorous acid.

Risks in Residential and Other Non-Occupational Environments

Risk to people from residential and other non-occupational environments is not expected as the new use is for greenhouse application and mono- and di-potassium salts of phosphorous acid has low toxicity.

Occupational Risks From Handling Confine Extra Fungicide

Occupational risks are not of concern when Confine Extra Fungicide is used according to the proposed label directions, which include protective measures.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label are considered adequate to protect individuals from occupational exposure. Since the application is done in a greenhouse by commercial applicators, exposure to bystanders is expected to be negligible.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Dietary risk to humans is considered negligible based on a long history of use and the low toxicity of the end use product. The available literature suggests that there is no toxicological concern from ingestion of the end-use product residues.

It is anticipated that the uses of mono- and di-potassium salts of phosphorous acid in Canada on food crops will not pose a risk to any segment of the population, including infants, children, adults and seniors, from consumption of produce from treated crops. The end-use product is registered for field uses in Canada for suppression of downy mildew and phytophthora diseases on potatoes, fruiting vegetables, blueberries, strawberries, grapes, brassicas, cucurbits, and leafy vegetables. PMRA did not specify MRLs (maximum residue levels) for mono- and di-potassium salts of phosphorous acid for the registered field uses.

No risk due to exposure from drinking water is anticipated as the end-use product is proposed for greenhouse application.

Environmental Considerations

What Happens When Mono- and Di-Potassium Salts of Phosphorus Acid Is Introduced Into the Environment?

Mono- and di-potassium salts of phosphorous acid are not expected to pose an unacceptable risk to the environment when used according to label directions as a fungicide in a greenhouse.

Mono- and di-potassium salts of phosphorous acid can enter the environment when used as a foliar-spray fungicide for food and non-food crops in greenhouses in Confine Extra Fungicide. Overall inputs to soil and water are considered to be less than the currently registered agricultural applications of this pesticide (i.e. field crops).

Mono- and di-potassium salts of phosphorous acid are not expected to pose an unacceptable risk to non-target terrestrial and aquatic species from use in greenhouses. This is based on the low toxicity to tested organisms and because environmental exposure is expected to be limited from use in greenhouses.

Value Considerations

What Is the Value of Confine Extra Fungicide on Greenhouse Tomatoes, Peppers, Cucumbers, Lettuce, Basil and Ornamentals?

Confine Extra Fungicide is a non-conventional fungicide with systemic properties that suppress major oomycete diseases, including downy mildews, on a wide range of crops. This product also poses a low risk of pest resistance development.

These characteristics make Confine Extra Fungicide a valuable option for integration into pest management practices. Potassium phosphite is identified as a high priority by Canadian growers for use against downy mildew on greenhouse cucumbers.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Confine Extra Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

To ensure bystander protection and mitigate postapplication exposure of workers, the end-use product label is required to include the precautionary statements, "Keep unprotected persons out of the treated areas in a greenhouse for the duration of the treatment period" and "Allow entry or re-entry to greenhouse only after thorough ventilation and spray mist has cleared and the treated surface has dried."

Environment

Precautionary label statements that are required for all commercial products will be needed. No other mitigative measures are necessary.

Next Steps

Before making a final registration decision on mono- and di-potassium salts of phosphorus acid, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on mono and di-potassium salts of phosphorus acid (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

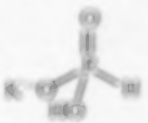
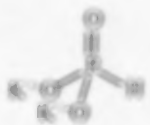
Science Evaluation

Mono and di-potassium salts of phosphorous acid

The original review for Winfield Phosphite TGAI and Confine Extra Fungicide can be found in Proposed Registration Decision PRD2012-25, *Mono- and Di-Potassium Salts of Phosphorous Acid* and Registration Decision RD2015-10, *Mono- and Di-Potassium Salts of Phosphorous Acid*

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	*Mono- and di-potassium salts of phosphorous acid*	
Function	Fungicide	
Chemical name		
1. **International Union of Pure and Applied Chemistry (IUPAC)**	Monopotassium phosphonate and Dipotassium phosphonate	
2. **Chemical Abstracts Service (CAS)**	Phosphonic acid, monopotassium salt and Phosphonic acid, dipotassium salt	
CAS number	Monopotassium phosphonate Dipotassium phosphonate	13977-65-6 13492-26-7
Molecular formula	Monopotassium phosphonate Dipotassium phosphonate	KH_2PO_3 K_2HPO_3
Molecular weight	Monopotassium phosphonate Dipotassium phosphonate	120.09 158.19
Structural formula	 13977-65-6	 13492-26-7
Purity of the active ingredient	99.0%	

6.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product — Winfield Phosphite TC 6.0

Property	Result
Colour and physical state	Colourless liquid
Odour	Faint
Melting range	Not applicable
Boiling point or range	100.0 °C
Density	1.468 g/mL
Vapour pressure at 20°C	The product is an aqueous liquid
Ultraviolet (UV)/visible spectrum	The product is not likely to absorb at $\lambda > 290$ nm
Solubility in water	Miscible
Solubility in organic solvents	Insoluble in organic solvents
n-Octanol-water partition coefficient (K_{ow})	Insoluble in n-octanol
Dissociation constant (pK_a)	$pK_{a1} = 1.580$ $pK_{a2} = 6.970$
Stability (temperature, metal)	Unstable to metal and metal ions (iron powder, ferric acetate, aluminum powder, aluminum acetate)

End-Use Product — Confine Extra Fungicide

Property	Result
Colour	Colourless
Odour	Faint
Physical state	Liquid
Formulation type	Solution
Guarantee	25.0 %
Container material and description	Poly containers, with capped poly inner, HDPE containers
Density	1.468 g/mL
pH of 1% dispersion in water	6.37
Oxidizing or reducing action	The product is neither an oxidant nor a reductant
Storage stability	Stable in HDPE containers at ambient temperatures
Corrosion characteristics	Not corrosive to HDPE packaging material
Explodability	The product is not expected to be explosive

6.3 Directions for Use

Confine Extra Fungicide is intended for suppression of several oomycete diseases on various greenhouse crops. Confine Extra Fungicide is to be applied in a preventative program, either as a foliar spray or soil drench treatment. For most foliar uses, five to nine applications at 5.0 L/ha are recommended on most crops. Drench applications are for use against phytophthora root rot and foliar blight on ornamentals.

6.4 Mode of Action

Mono- and di-potassium salts of phosphorous acid has systemic activity. The mode of action is both direct and indirect, and involves the induction of host plant resistance and the inhibition of oxidative phosphorylation in susceptible fungal pathogens.

7.0 Methods of Analysis

7.1 Methods for Analysis of the Active Ingredient

The methods provided previously for the analysis of the active ingredient and the impurities in Winfield Phosphite 0SAM have been validated and assessed to be acceptable for the determinations.

7.2 Method for Formulation Analysis

The method provided previously for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

8.0 Impact on Human and Animal Health

8.1 Toxicology Summary

Refer to PRD2011-27 and RRD2015-10 for a detailed summary of the toxicology of the technical product and the end-use product.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Incidents from Canada were searched for pesticide products containing the active ingredient mono- and di-potassium salts of phosphorous acid.

As of 28 November 2016, the PMRA received one human incident report, which was presented in PRD2011-27.

8.2 Occupational and Bystander Risk Assessment

8.2.1 Dermal Absorption

Dermal exposure is expected to be minimal due to the use pattern of the product and the method of application. Since the available literature suggests a negligible dermal absorption of mono- and di-potassium salts of phosphorous acid, and since adequate precautionary and hygiene statements are currently on the product label, a dermal absorption study was not considered necessary to complete the health hazard assessment of mono- and di-potassium salts of phosphorous acid.

3.2.2 Mixer, Loader, and Applicator Exposure and Risk

Occupational exposure to the mixer, loader, and applicator, as well as those responsible for clean-up and maintenance activities is anticipated to be minimal. Workers will be primarily exposed by both inhalation and dermal routes. Ocular exposure is also possible from splash during handling or from exposure to spray drift during application. Applicator exposure is of concern mainly when the end-use product is applied as a foliar spray using boomsprayers.

The end-use product label has a number of exposure reduction statements (for example, wearing of personal protective equipment, clothing, hygiene statement) to protect mixers, loaders and applicators against any unnecessary risk from exposure. The label instructs that applicators and other handlers must wear protective eyewear, long pants and long sleeved shirt, waterproof gloves, and shoes plus socks; also, avoid breathing of vapors or spray mist, avoid contact with eyes, skin or clothing; remove contaminated clothing and wash clothing before reuse, which should be effective in minimizing the potential for exposure.

Significant risk from exposure to mono- and di-potassium salts of phosphorous acid for the mixer, loader and applicator, as well as those responsible for clean-up, maintenance and repair activities is not anticipated due to the low toxicity of the active ingredient and reduced occupational exposure when label directions are followed.

3.2.3 Post-application Exposure and Risk

Post-application exposure is possible when workers enter the treated area in the greenhouse soon after the application, and it is of concern when such exposure happens without adequate protection. The primary exposure routes for re-entry workers/individuals are dermal from contact with freshly treated surfaces, ocular and inhalation exposures to spray mist if the area is not thoroughly ventilated or sufficient time was not given to let the suspended particles settle out of the air. Exposure may result in irritation to the eyes and the respiratory tract.

To ensure protection from post-application exposure, restricting entry/re-entry of workers into the greenhouse until the area is thoroughly ventilated, for suspended particles to settle, and treated surface is dried, is required as a precautionary measure.

3.2.4 Residential and Bystander Exposure and Risk

No residential exposure is expected from the proposed new uses. As the commercial application in the greenhouse involves only authorized personnel, bystander exposure is expected to be negligible when the end-use product is used according to the label directions.

3.3 Food Residue Exposure Assessment

3.3.1 Food and Drinking Water

Confine Extra Fungicide is proposed for treating tomatoes, peppers, basil, cucumbers, and lettuce in greenhouses for suppression of downy mildew and *Phytophthora*. A pre-harvest interval (PHI) of one day is proposed for greenhouse crops treated with the end-use product. The proposed greenhouse use pattern is identical to the existing registered field uses of the end-use product for suppression of downy mildew and *Phytophthora*. Since the application rates and frequency of applications for the new uses are not different from the already registered uses, a further assessment of food residue exposure is not required.

Refer to the PRD2012-25 or RD2013-10 for details related to the food residue exposure assessment of both the technical product and the end-use product.

As the new use is for greenhouse application and the end-use product is not to be applied near or directly to water, residues in drinking water are not anticipated.

3.3.2 Maximum Residue Limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as a MRL under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

PMRA did not specify an MRL for mono- and di-potassium salts of phosphorous acid for the registered field uses. Since the proposed greenhouse use is not likely to increase human dietary exposure to mono- and di-potassium salts of phosphorous acid, an MRL is not specified for the proposed greenhouse uses.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

For more information on the fate and behaviour in the environment of Winfield Phosphite TGAI and Confine Extra Fungicide, see PRD2012-25.

4.2 Environmental Risk Characterization

As for other uses, toxicity information for beneficial arthropods is requested for greenhouse use because bees and predatory and parasitic insects are often used in greenhouses for pollination and pest control services, respectively. As Winfield Phosphite TGAI and Confine Extra Fungicide are currently registered for field use on potatoes, fruiting vegetables, strawberries, grapes, brassicas, leafy vegetables, cucurbits, grapes, outdoor ornamentals and on stored potatoes, information on the toxicity to insects (honeybees) has been assessed in the previous

applications (see PRD2012-25), and showed that mono- and di-potassium salts of phosphorous acid are practically non-toxic to beneficial insects. Some exposure of aquatic systems may occur from greenhouses through disposal of wastewaters. However, based on previously submitted studies (see PRD2012-25), mono- and di-potassium salts of phosphorous acid demonstrates low toxicity to aquatic organisms.

A qualitative risk assessment was conducted for the proposed use in greenhouses. The proposed application rates for greenhouse use are similar to the registered application rates for field uses and the exposure of non-target organisms in the environment to mono- and di-potassium salts of phosphorous acid is expected to be limited when compared to field uses. Based on the low toxicity of mono- and di-potassium salts of phosphorous acid demonstrated to tested species, and the limited exposure following its use in a greenhouse, the risk to beneficial insects and to aquatic organisms is expected to be negligible.

5.0 Value

5.1 Consideration of Benefits

Confine Extra Fungicide is a non-conventional fungicide with systemic properties that suppress oomycete diseases, including downy mildews, on a wide range of crops. This product also poses a low risk of pest resistance development. These characteristics make Confine Extra Fungicide a valuable option for integration into agricultural pest management practices with other conventional fungicides to suppress the listed diseases and to reduce the inoculum mass.

Alternative conventional and non-conventional fungicides exist for most of the registered crops on the Confine Extra Fungicide label (refer to Table 1, Appendix I, for a summary of the active ingredients currently registered for control or suppression of listed diseases). However, either few, or no fungicides are registered for certain crop/disease combinations for which the registration of Confine Extra Fungicide will provide a much needed alternative. Potassium phosphite is a high grower priority in the Canadian Grower Priority Database for use against downy mildew on greenhouse cucumbers. In addition, mono- and di-potassium salts of phosphorous acid could contribute to the solution for two high priorities i.e. downy mildew on greenhouse ornamentals and *Phytophthora* on greenhouse peppers.

5.2 Effectiveness Against Pests

Value information was provided in the form of scientific rationales, experimental trials and published literature. The scientific rationale stated that the available efficacy data generated from various formulated products containing mono- and di-potassium salt of phosphorous acid were sufficient to demonstrate the efficacy of phosphites for these pests under field conditions and should translate to the same efficacy under greenhouse conditions.

The applicant has also provided some studies that demonstrate the efficacy of Confine Extra Fungicide under greenhouse setting. An experimental trial, for the management of basil downy mildew (*Peronospora belbahrii*) under greenhouse conditions in Florida, was submitted. The results demonstrated that the phosphite fungicide used in the trial reduced downy mildew severity by 77 to 100%, and incidence by 52 to 55%, when compared to the untreated inoculated control. These results are comparable to the results obtained with the basil field trials submitted

previously. In addition, published literature on the use of phosphite fungicides for the management of greenhouse petunia and tomato late blight (*Phytophthora infestans*), and greenhouse hydrophonic pepper, for suppression of phytophthora demonstrated the suppressive effect of mono- and di-potassium salts of phosphorous acid on *Phytophthora* on greenhouse tomatoes and peppers.

5.3 Non-Safety Adverse Effects

Plant injury may occur under certain circumstances when using Confine Extra Fungicide. Mono- and di-potassium salts of phosphorous acid may increase the uptake of certain metals into plants, thus, care must be taken when using tank mixes containing pesticide products with a metal base. In addition, where phosphite is used on soils where there is an excess of phosphorous acid alkali metal salts, phosphate starvation may result. Finally, crop varieties may vary in their tolerance to mono- and di-potassium salts of phosphorous acid. Label statements to inform the users on the risks and prevention measures appear on the product label.

5.4 Supported Uses

The claims of suppression of phytophthora foliar blight (*Phytophthora capsici*, *P. nicotianae*) on greenhouse cucumbers, phytophthora foliar blight (*Phytophthora* spp.) on greenhouse tomatoes and greenhouse peppers, as well as downy mildew (*Peronospora lamii*) on greenhouse ornamentals, are supported.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, mono- and di-potassium salts of phosphorous acid were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

> Mono- and di-potassium salts of phosphorous acid does not meet Track 1 criteria, and is not considered a Track 1 substance and are not expected to bioaccumulate in the environment.

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[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade mono- and di-potassium salts of phosphorous acid, Winfield Phosphite TGAI, and the end-use product, Confine Extra Fungicide, do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

7.0 Summary

7.1 Human Health and Safety

The toxicology profiles of the technical product and the end-use product are as characterized in the original review. They are of low acute toxicity irrespective of the route of exposure and minimally irritating to the eyes.

Although occupational exposure is expected, the precautionary statements on the end-use product label are sufficient to minimize any risk due to exposure of workers and bystanders.

Exposure to mono- and di-potassium salts of phosphorous acid from the diet or drinking water is not expected to be of concern. Maximum residue limits for mono- and di-potassium salts of phosphorous acid were not required at this time.

7.2 Environmental Risk

The use of mono- and di-potassium salts of phosphorous acid as a fungicide, according to the label of Confine Extra Fungicide, is not expected to pose a risk to terrestrial or aquatic non-target organisms.

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6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

7.3 Value

The value information submitted to register greenhouse uses on Confine Extra Fungicide is adequate to demonstrate value, including efficacy, for use on the labelled crops and diseases. Confirmatory value information is required for certain claims (Appendix 1, Table 2).

Confine Extra Fungicide is a non-conventional fungicide with systemic properties that suppress major oomycete diseases, including downy mildews, on a wide range of crops. This product also poses a low risk of pest resistance development. These characteristics make Confine Extra Fungicide a valuable option for integration into agricultural pest management practices.

Potassium phosphite is a high grower priority in the Canadian Grower Priority Database for use against downy mildew on greenhouse cucumbers. In addition, mono- and di-potassium salts of phosphorous acid could contribute to the solution for two high priorities i.e. downy mildew on greenhouse ornamentals and *Phytophthora* on greenhouse peppers.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Winfield Phosphite TGAI and Confine Extra Fungicide, containing the technical grade active ingredient mono- and di-potassium salts of phosphorous acid, to suppress major oomycete diseases on a range of crops and ornamentals in greenhouses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

λ	wavelength
>	greater than
℃	degrees Celsius
CAS	Chemical Abstracts Service
DIR	Regulatory Directive
FDA	*Food and Drugs Act*
g	gram(s)
ha	hectare(s)
HDPE	High density polyethylene
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	*n*–octanol-water partition coefficient
L	litre
mL	millilitre(s)
MRL	maximum residue limit
N/A	not applicable
nm	nanometre(s)
NOI	Notice of Intent
PCPA	*Pest Control Products Act*
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
poly	polyethylene
PRD	Proposed Registration Decision
PVC	polyvinylchloride
RD	Registration Decision
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Registered Alternatives (as of December, 2014)

Crop / Crop group	Disease	Active Ingredient and Resistance Management Group
Greenhouse Tomatoes	Late blight	mandipropamid (40) *garlic powder *Bacillus subtilis strain QST 713 (44) *Bacillus subtilis var. amyloliquefaciens strain FZB24 (44) copper (M1) mancozeb (M3) tea tree oil
Greenhouse Peppers	Late blight	N/A
Greenhouse Tomatoes	Phytophthora foliar blight	*Streptomyces sp.
Greenhouse Peppers	Phytophthora foliar blight	mandipropamid (40) *Streptomyces sp.
Greenhouse Basil	Downy mildew	cyazofamid (21)
Greenhouse Lettuce	Downy mildew	fosetyl-al (U) mandipropamid (40) *Bacillus subtilis strain QST 713 (44)
Greenhouse cucumbers	Phytophthora foliar blight	N/A
	Downy mildew	mandipropamid (40) *garlic powder *citric acid + lactic acid *tea tree oil cyazofamid (21) propamocarb hydrochloride (28) *Bacillus subtilis strain QST 713 (44) mancozeb (M3)
Greenhouse Ornamentals	Phytophthora root rot and foliar blight	metalaxyl (4) fosetyl-al (U) propamocarb hydrochloride (28) *Bacillus subtilis strain QST 713 (44) *Streptomyces sp.
	Downy mildew	dimethomorph (40)

* Products classified as non-conventional pesticides.

Table 2 List of Supported Uses

Use Claims Accepted, submitted value information support use

Proposed label claim	Supported use claim
Late blight (*Phytophthora infestans*) / **Greenhouse Tomatoes** / Apply CONFINE EXTRA Fungicide at a rate of 5-10 L/ha in a minimum of 1000 L water/ha	*Accepted as proposed*
Late blight (*Phytophthora infestans*) / **Greenhouse Peppers**/ Apply CONFINE EXTRA Fungicide at a rate of 5-10 L/ha in a minimum of 1000 L water/ha	*Accepted as proposed*
Downy mildew (*Pseudoperonospora hulbahrii*)/ **Greenhouse Basil**/ Apply CONFINE EXTRA Fungicide at a rate of 3-9 L/ha in a minimum of 1000 L water/ha	*Accepted as proposed*
Downy mildew (*Bremia lactucae*)/ **Greenhouse Lettuce**/ Apply CONFINE EXTRA Fungicide at a rate of 3-7 L/ha in a minimum of 1000 L water/ha	*Accepted as proposed*
Downy Mildew (*Pseudoperonospora cubensis*)/ **Greenhouse Cucumbers**/ Apply CONFINE EXTRA Fungicide at a rate of 3-5 L/ha in a minimum of 1000 L water/ha	*Accepted as proposed*
Phytophthora root rot and foliar blight (*Phytophthora* spp., except *P. ramorum, P. cryptogea*)/ **Greenhouse Ornamentals**/ Apply CONFINE EXTRA Fungicide at a rate of 1.3 L/1000 L water	*Accepted as proposed*

Use claims accepted on the condition that additional value information be provided.

Proposed label claim	Supported on the condition that additional value information be provided
Phytophthora foliar blight (*Phytophthora capsici, P. nicotianae*)/ **Greenhouse Cucumbers**/ Apply CONFINE EXTRA Fungicide at a rate of 5-6 L/ha in a minimum of 1000 L water/ha	*Accepted as proposed* with conditions that are attached to the original review Confirmatory information is required to demonstrate the value of Confine Extra Fungicide, when applied at the proposed rates and timing, in suppressing phytophthora foliar blight (*Phytophthora capsici, P. nicotianae*) on cucurbits. The confirmatory information is to be provided to the Agency by September 1, 2018.
Phytophthora foliar blight (*Phytophthora* spp.)/ **Greenhouse Tomatoes & Greenhouse Peppers**/ Apply CONFINE EXTRA Fungicide at a rate of 5-10 L/ha in a minimum of 1000 L water/ha	*Accepted as proposed* with conditions that are attached to the original review Confirmatory information is required to demonstrate the value of Confine Extra Fungicide, when applied at the proposed rates and timing, in suppressing phytophthora foliar blight (*Phytophthora* spp.) on greenhouse tomatoes and greenhouse peppers. The confirmatory information is to be provided to the Agency by September 1, 2018.

Proposed label claim	Supported on the condition that additional value information be provided
Downy mildew (*Peronospora lamii*) / **Greenhouse Ornamentals**/ Apply CONFINE EXTRA Fungicide at a rate of 1.5 L/1000 L water	*Accepted as proposed with conditions that are attached to the original review.* Confirmatory information is required to demonstrate the value of Confine Extra Fungicide, when applied at the proposed rates and timing, to suppressing downy mildew (*Peronospora lamii*) on greenhouse ornamentals. The confirmatory information is to be provided to the Agency by September 1, 2016.

References

9. List of Studies/Publications Submitted by Registrant

9.8 Human and Animal Health

MRID # or Publication Number	Reference
2300[illegible]	(1998). 2016. Use Description/Scenario (application and post-application). DACO 9.2

9.9 Environment

MRID # or Publication Number	Reference
1[illegible]000	2000. Environmental Chemistry Waiver. Waiver DACO 9.1
1[illegible]0000	2000. Environmental Toxicology Waiver. Waiver DACO 9.1
1[illegible]2[illegible]2	2010. Waiver DACO Part 9. DACO 9.1, 9.2.8.1, 9.2.8.2, 9.2.8.3, 9.2.8.5, 9.2.9, 9.2.9.1, 9.2.9.2, 9.2.9.3, 9.2.9.4, 9.2.9.5, 9.2.9.6, 9.2.9.7, 9.2.9.8, 9.2.9.9, 9.2.9.10, 9.2.9.11, 9.2.9.12, 9.2.9.13, 9.2.9.14, 9.2.9.15, 9.2.9.16, 9.2.9.17, 9.9.8
1[illegible]2[illegible]3	2010. Terrestrial Vascular Plant Waiver. Waiver DACO 9.9.8

9.9 Water

MRID # or Publication Number	Reference
2300[illegible]49	2013. Efficacy waiver. DACO 10.2.5.3(ii)(b)
2300[illegible]47	2013. Safety offsets. DACO 10.5.2
2300[illegible]47	2013. Pest problem. DACO 10.2.2
2300[illegible]50	P. Wardle, S. Zhang and X. Mu. 2010. Evaluation of biological and biorational's for control of basil downy mildew under greenhouse conditions. Plant Disease Management Reports, 4: V[illegible]59. DACO 10.2.5.3(ii)(b)
1[illegible]70520	W.C. Bockstl, W.E. Daughtrey and W.E. Fry. 2007. Epidemiology and management of petunia and tomato late blight in the greenhouse. Plant Disease, 80(10): 1080-1088. DACO 10.2.5.5
1[illegible]70530	H. Furuya, J.E. Adaskaveg, D.H. Kim and M. Strongbellin. 1998. Effect of phosphite on tomato and pepper plants and on susceptibility of pepper to phytophthora root and crown rot in hydroponic culture. Plant Disease, 82(10): 1165-1170. DACO 10.2.5.5
2300[illegible]48	2013. Survey of alternatives. DACO 10.5.1